



Biotech Daily

Monday September 26, 2011

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: ANTISENSE UP 12.5%; PRIMA DOWN 11%**
- * **VIRALYTICS' CAVATAK KILLS B-RAF RESISTANT MELANOMA IN-VITRO**
- * **PATRY'S NAMES PAT-SM6 ACTIVE AGAINST MULTIPLE MYELOMA**
- * **CBIO BOARD ATTACKS ACTION GROUP OVER SPILL EGM**
- * **PROGEN: MEDIGEN DOSES 1st PI-88 PHASE III LIVER CANCER PATIENT**
- * **ACTINOGEN VOTES TO ACQUIRE CELGENICS**
- * **BPH: CORTICAL DYNAMICS IPO EXTENDED TO JANUARY 2012**
- * **MARK SCOTT CEASES ENTIRELY IN IM MEDICAL**
- * **STARPHARMA APPOINTS ZITA PEACH NON-EXECUTIVE DIRECTOR**

MARKET REPORT

The Australian stock market fell 1.01 percent on Monday September 26, 2011 with the S&P ASX200 down 39.3 points to 3,863.9 points. Just three of the Biotech Daily Top 40 stocks were up, 23 fell, seven traded unchanged and seven were untraded. All three Big Caps were up.

Antisense was best, up 0.1 cents or 12.5 percent to 0.9 cents with 14.9 million shares traded.

Viralytics climbed 3.4 percent; CSL and Heartware rose two percent or more; with Cochlear and Resmed up more than one percent.

Prima led the falls, down two cents or 11.4 percent to 15.5 cents with 8.5 million shares traded.

Benitec and Nanosonics lost more than nine percent; Phylogica and QRX were down more than eight percent; Acrux fell 7.05 percent; Patrys and Prana were down more than six percent; Allied Health, Impedimed, Sunshine Heart and Tissue Therapies fell five percent or more; Reva lost 4.6 percent; Anteo, Circadian, Genetic Technologies, Pharmaxis and Sirtex were down more than three percent; Clinuvel and Mesoblast shed more than two percent; with LBT, Living Cell and Starpharma down more than one percent.

VIRALYTICS

Viralytics says pre-clinical studies show that Cavatak has potent oncolytic activity against resistant melanoma cells in vitro.

Viralytics said the studies showed that Cavatak was effective against melanoma cells that were resistant to selective b-rapidly accelerated fibrosarcoma (b-Raf) kinase inhibitors, including the recently US Food and Drug Administration-approved B-Raf kinase inhibitor melanoma treatment, vemurafenib, marketed as Zelboraf by Hoffman-La Roche.

Viralytics managing director Bryan Dulhunty told Biotech Daily that the pre-clinical work was a study of treatment-resistant human cell lines in vitro.

The company said the data would be presented as a poster entitled 'Cavatak (Coxsackievirus A21) displays potent oncolytic activity in BRAFV600E mutant melanoma cells which show resistance to selective BRAF kinase inhibitors' by Chief Scientific Officer Dr Darren Shafren at the Society for Melanoma Research meeting in Tampa, Florida, November 9-11, 2011.

Viralytics said that vemurafenib was a small molecule drug designed to selectively inhibit the mutated B-Raf V600E kinase which occurred in the melanoma cells of about 50 percent of patients.

The company said the preliminary pre-clinical data suggested that Cavatak could possess the potential to work in combination or in sequential regimes with vemurafenib in mediating direct killing of malignant melanoma cells.

Viralytics said that Roche was pursuing a broad development program with verurafenib including additional research with combination treatments.

Viralytics was 1.5 cents or 3.4 percent to 46 cents.

PATRYS

Patrys says its lead anti-cancer antibody PAT-SM6 is the previously unnamed compound showing significant activity in preclinical studies of multiple myeloma.

Last month Patrys said that preclinical work at the University Hospital of Würzburg showed activity of one of its compounds for multiple myeloma, but Patrys chief executive officer Dr Marie Roskrow told Biotech Daily the name of the compound had not been released due to intellectual property concerns (BD: Aug 17, 2011).

Today, Patrys said the compound was lead antibody PAT-SM6.

In August, the University Hospital of Würzburg's Dr Leo Rasche said that a major obstacle in the treatment of multiple myeloma was disease recurrence "due in part to the outgrowth of chemotherapy and novel agents-resistant plasma cells".

"This study shows that [PAT-SM6] can specifically bind to multiple myeloma cells from both patients at the stage of primary diagnosis and also in relapsed individuals," Dr Rasche said.

A phase I trial of PAT-SM6 for melanoma is near completion at the Royal Adelaide Hospital (BD: Jul 25, 2011), the compound has been shown to prevent colon cancer metastases in a series of preclinical animal studies (BD: Sep 16, 2009) and mouse studies had shown potential efficacy against ovarian and prostate cancer (BD: Sep 20, 2011).

Today, Patrys said that Dr Rasche's in-vitro, human cell line work produced data "strong enough for us to consider looking at an additional trial in treatment-resistant multiple myeloma".

"A trial in patients with this disease is attractive from a development perspective as it is possible to determine very quickly whether the product is working by assessing routine blood counts and bone marrow samples," Dr Roskrow said.

Patrys fell 0.4 cents or 6.8 percent to 5.5 cents.

CBIO

All nine CBio directors have signed a unanimous recommendation to reject resolutions to a requisitioned extraordinary general meeting to spill three directors.

Earlier this month, the shareholder action group said it wanted to replace chairman Stephen Jones and directors Prof John Funder and James Greig with of former Amrad director and Avexa chair Helen Cameron, Ergon Energy chairman Dr Ralph Craven and Warren Brown (BD: Sep 5, 7, 2011).

In the notice of meeting CBio warned shareholders of the risks of changing board members.

"Be very clear - these resolutions and the on-going campaign that has been undertaken by this group, both prior to and subsequent to the delivery of their requisition notice, is damaging to CBio and a slur on each of us who acts as a director on your board," the CBio directors said.

"At this crucial time for the company, the actions by the requisitioning shareholders are destabilizing and disruptive and obviously intended to be so," the directors said.

"Their actions threaten the future prospects of the company and thus the prospects for all shareholders," the CBio directors said.

CBio said the requisitioning shareholders provided a statement "which would normally be included with this notice of meeting, but CBio has legal advice confirming that their statement is defamatory" and the statement was not included.

"It is nothing other than mere speculation to believe that any of the proposed board changes could be positive," the directors said. "To the contrary, changes proposed as a result of these resolutions present new risks that otherwise don't exist for the company."

"For the other 94.4 percent of the company's shareholders who are not part of the requisitioning shareholders, you should be very concerned and consider your position in relation to these resolutions carefully," the CBio directors said.

The CBio action group's spokesman Alan Baker said earlier this month that the group wanted "to provide shareholders with an opportunity to rejuvenate the board with a view to improving CBio's record of communication with shareholders and the market, [and improve] capital management and corporate governance.

Mr Baker is an associate director of the Brisbane-based Retirewell Financial Planning.

The media release was signed by Alan and Julie Baker, Tony and Marie Gillett, Warren and Roslyn Brown, Morten Weaver, Jane Duncan and Pella Comino, most of whom were named as substantial shareholders in a notice to the ASX on Monday (BD: Sep 5, 2011).

"We consider that the market is significantly undervaluing CBio at present because of an inadequate announcement on July 31, 2011 by CBio regarding the interim results of the recently completed phase IIa trial," Mr Baker said (BD: Aug 1, 2011).

"The announcement did not provide investors with full and complete information regarding the trial and led to the misconception that the trial was not a success, which consequently drove down the share price by around 60 percent," Mr Baker said.

Mr Baker said that missing the primary endpoint was the result of under-dosing.

Mr Baker said that best practice in corporate governance was having an independent chairman and separating the roles of chief executive and chairman.

"The removal of Mr Jones, who has chaired the company since its inception more than 10 years ago, will achieve this," Mr Baker said. "While we believe that major shareholders will support the rights issue ... we are dismayed at the board's actions in diluting shareholders unnecessarily by raising more capital than is essential at such a low price."

The meeting will be held at the Central Auditorium, Brisbane Technology Park, 1 Clunies Ross Court, Eight Mile Plains, Queensland on November 4, 2011 at 10am (AEST).

CBio fell half a cent or 2.6 percent to 19 cents.

PROGEN PHARMACEUTICALS

Progen says Taiwan licensee, Medigen has treated its first patient in its phase III clinical trial of PI-88 for hepatocellular carcinoma, triggering a \$US500,000 payment.

Progen said patient recruitment had begun at three sites in Taiwan, with more sites expected to be initiated soon.

The company said the study was designed to confirm the efficacy and safety of PI-88 in the adjuvant treatment of hepatocellular carcinoma or liver cancer after surgical resection and was a randomized, placebo-controlled, multinational trial with disease-free survival the primary endpoint for efficacy assessment (BD: Apr 30, 2010; Jun 23, 2011).

Progen chairman Stuart James said the commencement of patient recruitment "is a significant milestone in the development of PI-88 and reflects the hard work and cooperation between Medigen, Pharmasynth and Progen".

The company said that the November 2009 settlement agreement between Progen, Medigen and other Progen shareholders had been completed and the undertakings had expired.

Progen was untraded at 20 cents.

ACTINOGEN

Actinogen says shareholders at its extraordinary voted for the acquisition of Celgenics

Actinogen said the West Australian-based Celgenics was focused on the discovery of actinomycetes from the West Australian environment that have the capacity to kill cancer stem cells that can remain in the human body after currently available chemotherapy.

Actinogen said it intended to develop its newly acquired technologies to investigate the abilities of actinomycetes to direct the development and/or modify the maturation pathways of stem cells in general.

In a presentation to its 2010 annual general meeting Actinogen said it isolated a group of gram positive bacteria, mainly from the soils of Western Australia, which had "a wide-ranging ability to mobilize metabolic pathways and to utilise many unusual sources of nutrients".

The company said the gram positive bacteria "produce many bioactive molecules ... many including antibiotics, anti-fungal agents, anti-cancer agents as well as isolates that are useful in agriculture, mining and bioremediation processes".

Actinogen said it would use Celgenics' resources, including its actinomycetes library, to integrate these into its research and development programs investigating abilities of actinomycetes to produce anti-cancer bio-molecules.

Actinogen was untraded at 3.1 cents.

BPH ENERGY, CORTICAL DYNAMICS

BPH says the initial public offer of 3.6 percent subsidiary Cortical Dynamics has been extended from September 26, 2011 to January 31, 2012.

BPH said "the continued market volatility" was the reason for the second extension of the offer to raise up to \$4 million to commercialize its brain anaesthesia.

The company first extended the offer in August (BD: Aug 16, 2011).

The company said it was offering up to 10 million shares at 20 cents each with attaching options exercisable at 20 cents by September 30, 2012 with oversubscriptions for a further 10 million shares and options on the same terms.

A copy of the prospectus can be downloaded at www.corticaldynamics.com.

BPH was up 0.1 cents or 2.9 percent at 3.5 cents.

IM MEDICAL

Mark Scott has sold his entire 56,447,604 shares or 51.05 percent of IM Medical.

Mr Scott said he sold the shares for \$959,609 or 1.7 cents a share.

Last month, IM Medical withdrew resolutions to sell the radiology business and approve a rights issue, while a resolution to issue shares and options relating to converting loans was defeated (BD: Aug 17, 2011).

Mark Scott Group radiology acquired IM Medical but the company saw a raft of board changes and dissent at meetings, which followed IM's inability to commercialize its Intelliheart cardiac testing system (BD: Jun 20, 2008; Jun 10, 30, Nov 22, 2010; Feb 7, Mar 10, 2011).

IM Medical last untraded at five cents.

STARPHARMA HOLDINGS

Starpharma says Zita Peach will be appointed as a non-executive director from October 1, 2011.

Starpharma said Ms Peach had more than 20 years of commercial experience in the pharmaceutical industry, particularly in marketing and business development, working for CSL and Merck Sharp & Dohme, the Australian subsidiary of Merck Inc.

The company said Ms Peach had experience in pharmaceutical marketing, commercialization of pharmaceutical portfolios, acquisitions and international partnering. Starpharma said that at CSL, Ms Peach was head of business development, where she oversaw commercialization of CSL's early stage research and development portfolio and licencing agreements and was involved in due diligence and acquisitions including Zenyth and Aventis Behring.

The company said Ms Peach was the managing director of infusion therapy and clinical nutrition company Fresenius Kabi.

Starpharma said Ms Peach was a board member of Bio-Melbourne Network and a non-executive director of Vision Group Holdings.

Starpharma fell 1.5 cents or 1.4 percent to \$1.09.